IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

In re: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	)	MDL No. 2545
	)	Master Docket Case No. 1:14-cv- 01748
	)	Honorable Matthew F. Kennelly
This Document Relates To: *Kibat v. AbbVie Inc., et al.* Case No. 1:15-cv-08820	)	

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF ABBVIE'S MOTION FOR SUMMARY JUDGMENT IN *KIBAT*

Pursuant to Rule 56.1 of the Local Civil Rules of the United States District Court for the Northern District of Illinois, Defendants AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, and Unimed Pharmaceuticals, LLC (collectively "AbbVie") respectfully submit this statement of undisputed material facts in connection with Defendants' Motion for Summary Judgment.

THE PARTIES

1. The Plaintiff is George Kibat who was an Iowa resident when he was prescribed and used AndroGel in Iowa and was treated for his heart attack allegedly caused by AndroGel in April of 2012. Ex. A, KIBATGR-6PFS-00003 to -00024.

2. Defendant AbbVie Inc. is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

3. Defendant Abbott Laboratories is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbott Park Road, North Chicago, Lake County, Illinois 60064.

4. Defendant AbbVie Products LLC f/k/a Solvay Pharmaceuticals, Inc. is a limited liability company whose sole member is AbbVie Inc.

5. Defendant Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. is a limited liability company whose sole member is AbbVie Products LLC.

VENUE AND JURISDICTION

6. AbbVie is located in Lake County, Illinois, which is within the judicial boundaries of the Northern District of Illinois. Venue is proper under 28 U.S.C. § 1391.

7. Plaintiff seeks damages in excess of $75,000. There is total diversity of citizenship between the parties, and this Court has jurisdiction under 28 U.S.C. § 1332.

STATEMENT OF UNDISPUTED FACTS

8. Plaintiff filed his Master Short-Form Complaint for Individual Claims directly into the MDL on October 5, 2015. *See* Doc. 1.

9. On August 10, 2010, Plaintiff presented to his primary care physician, Dr. Neil Sheppard, complaining of fatigue, "decreased energy, decreased motivation and weariness," and Dr. Sheppard ordered testosterone levels the same day. Ex. B, KIBATGR-49WBC-00589.

10. Plaintiff's free and total testosterone laboratory results returned on August 11, 2010 were below normal levels. KIBATGR-49WBC-00843.

11. On August 23, 2010, Dr. Sheppard administered an injection of Depo-Testosterone during an office visit. KIBATGR-49WBC-00588.

12. Plaintiff again presented to Dr. Sheppard's office with complaints of moderate fatigue on July 22, 2011. KIBATGR-49WBC-000564 to -568.

13. During the July 22, 2011 visit, Dr. Sheppard noted that previous tests had revealed low testosterone levels, and he diagnosed Plaintiff with "Fatigue/Malaise" and "[d]eficiency of testosterone biosynthesis NOS." KIBATGR-49WBC-000567.

14. Plaintiff received an injection of Testosterone Cypionate in the office on July 22, 2011. KIBATGR-11WBC-00137.

15. On August 5, 2011, Dr. Sheppard initially prescribed "AndroGel 5g/packet transdermal gel." KIBATGR-49WBC-00561 to -564.

16. Dr. Sheppard regularly prescribed AndroGel from August 5, 2011 to April of 2012. Ex. E, Sheppard Dep. 21:11–17 (April 10, 2018).

17. On April 5, 2012, Plaintiff was admitted to the hospital with complaints of chest pain. KIBATGR-31CHIHMCB-00465 to -468. An electrocardiogram showed an ST-elevation myocardial infarction. KIBATGR-31CHIHMCB-00466.

18. After a successful cardiac catheterization, Plaintiff was discharged home on April 7, 2012 in stable condition with a diagnosis of acute anteroseptal ST-segment elevation myocardial infarction. KIBATGR-31CHIHMCB-00462 to -464.

19. Dr. Sheppard continued to prescribe AndroGel from April 2012 to February 2013. Sheppard Dep. 22:4–13

20. Plaintiff voluntarily discontinued AndroGel because his health insurance would not pay for it; Dr. Sheppard did not take Plaintiff off AndroGel. KIBATGR-49WBC-00810 to -811; Sheppard Dep. 153:21–154:14.

21. In prescribing AndroGel for Plaintiff, Dr. Sheppard followed his standard prescribing habits, including to prescribe a topical testosterone product "[based on] whichever

one worked out best for the patient's insurance . . . ," rather than based on product labels, marketing materials, or sales representatives' statements. Sheppard Dep. 64:3–20.

22. Although Dr. Sheppard has "a baseline familiarity with the [AndroGel] product label," he did not take the safety and efficacy information provided by the company "on face value." Sheppard Dep. 58:19–59:13. Instead he "tend[s] to refer more to literature when [he] look[s] at medication. And that includes risk and benefits." *Id.* at 60:12–24. He believes that there are some potential side effects of medication that are listed in drug labels that are based on faulty studies, that are not true, "but they are listed by the FDA." *Id.*

23. In May of 2015, the FDA directed AbbVie to include (1) a limitation of use section regarding age-related hypogonadism; and (2) a warning regarding the association of AndroGel and cardiovascular risk. Ex. F, AndroGel 1% Label, May 2015 (Ex. 10 to Sheppard Dep).

24. Dr. Sheppard would not have changed his decision to prescribe AndroGel in light of the limitation of use regarding age-related hypogonadism. *See* Sheppard Dep. 92:16–93:1; 98:1–24; 99:8–11; 100:4–8; 106:17–108:21.

25. Dr. Sheppard would not have changed his decision to prescribe AndroGel in light of the 2015 "warning" regarding cardiovascular risk because the literature commenting on this connection was inconclusive and unreliable. *See* Sheppard Dep. 73:8–76:3; 110:8–18.

26. Dr. Sheppard did not rely on AbbVie's warnings or any marketing information or materials provided by AbbVie or its sales representatives in diagnosing Plaintiff with idiopathic, secondary hypogonadism or determining whether to prescribe AndroGel for patients like Plaintiff; rather, he relied on his own education, training, clinical experience, and medical judgment. *See* Sheppard Dep. 14:3–24; 34:21–35:2; 38:4–39:18; 40:5–41:18; 44:12–15; 45:11–

46:4; 49:11–25; 50:17–25 57:20–58:10; 58:29–59:13; 60:12–24; 64:3–20; 67:12–68:6; 69:8–13; 98:21–100:10; 125:3–11.

27. Plaintiff did not rely on information contained in any AndroGel advertisements and did not request AndroGel from Dr. Sheppard as a result of viewing those advertisements, deferring to Dr. Sheppard and exclusively relying on Dr. Sheppard's medical judgment in prescribing medication for him. Ex. G, Kibat Dep. 57:14–66:11; 199:7–19 (Feb. 28, 2018).

28. On April 16, 2018, Plaintiff identified Charleston J. Gbur, Jr., M.D. as his only case-specific expert witness, and he was deposed on May 15, 2018. *See* Ex. C, Expert Report of Charleston J. Gbur, Jr., M.D. FACC, GSCAI; Ex. D, Gbur Dep. (May 15, 2018).

Dated: June 14, 2018

Respectfully submitted,

/s/ Alicia J. Donahue

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Alicia J. Donahue
Alicia J. Donahue